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WITNESS my hand this
Sixteenth day of September 1999

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AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Applicant(s):

THE LIONS EYE INSTITUTE OF WESTERN AUSTRALIA INCORPORATED

Invention Title:

SURGICAL VISUAL FEEDBACK AND EYE FIXATION METHOD AND APPARATUS

The invention is described in the following statement:

SURGICAL VISUAL FEEDBACK AND EYE FIXATION METHOD AND APPARATUS

The present invention relates to methods and apparatus for providing visual feedback to a surgeon and eye fixation during the delivery of medical laser procedures, particularly in the fields of ophthalmic surgical procedures, such as Photorefractive Keratectomy (PRK) and Laser-in-situ Keratomileusis (LASIK), or any laser based refractive correction. The invention will be described with reference to these applications, though it is to be understood that other applications are envisaged.

Most existing refractive laser delivery systems provide little feedback for the operator (typically a surgeon). Usually a crosshair graticule is superimposed through the microscope optics to help the operator aim the laser beam correctly onto the cornea. A fixation target or light, such as a flashing LED, is used to ensure that the patient's eye remains correctly aligned during the surgery. However, this arrangement does not necessarily provide the best alignment of the eye and the laser beam, nor does it provide visual feedback for the operator concerning the status of the eye or the laser. It may at times be necessary for the operator to move his or her attention away from the surgical field to check on instrumentation, such as the microkeratome or the laser source. The axis of astigmatism of the patient's eye is also likely to be misaligned when the patient is supine and fixating on a point of light.

Refractive errors are usually assessed when the patient is seated in an upright position using structured shapes or symbols, such as letters of the alphabet. However, refractive surgery is usually performed with the patient reclining in an operating chair. It has been found that, when a patient lies recumbent, the ocular globe is liable to rotate, altering the

position of the axis of astigmatism by between 7° and 16° in 25% of cases (Smith, Talamo, Assil & Petashnick, 1994). This occurs for two reasons: i) the removal of the reference horizon, and ii) the change from binocular to monocular vision. Focussing on a point of light (the flashing LED), instead of the linear horizon, does not provide a proper point of horizontal or vertical reference. The globe is therefore liable to rotate fractionally, possibly resulting in misalignment of the treatment of the eye's axis of astigmatism. The potential end result is under-treatment of the original astigmatic error or inducement of astigmatism at another axis.

US Patent 5,549,597 describes a method for determining the axis of astigmatism of a patient undergoing refractive surgery and the precise alignment of the laser beam with that axis. The patient is required to focus on a target such as three sets of three lines of variable width, each set corresponding to a different visual acuity, and then to focus on the best resolved set of lines and rotate the target until the finest line is seen most clearly. However, this method of determining the axis of astigmatism and aligning the surgical laser is not ideal. The patient is forced to make subjective comparisons at a highly stressful time. In addition, the globe may still rotate after the alignment has been performed, and prior to surgery.

Corresponding to the patient fixation apparatus is the apparatus used by the surgeon to view and assess the extent of fixation and the alignment of the laser beam. The surgeon views this display when looking down the surgical microscope. Current technology provides a display including a graticule or crosshair. A He-Ne beam is sometimes provided for aiming the surgical beam. However, a more informative head-up display could be provided to project data in front of the eye to be operated on, so that the surgeon could focus either on the

plane of the cornea or the plane of the information. Such a display could aid in the assessment of eye fixation, operating parameters, or the status of the equipment, without requiring the surgeon to move his gaze from the operating field. A head-up display could also be made to display information pertinent to the laser or the patient, for example, laser on/off conditions, a pulse countdown, and the surgical aim. With an active eye tracker in operation, the surgeon may be unaware where the laser is pointing (i.e. where the tracker locates the eye). The head-up display could display a cross to indicate the tracker is pointing the laser, allowing the surgeon to check that the tracker is operating correctly.

US Patent 4,870,964 provides a head-up display for use with an operating microscope during phaco-emulsification procedures. This apparatus allows the operating surgeon to view information about the status of the patient, the eye and operating equipment, such as vacuum pressure, without removing their gaze from the operating field. It does so by projecting light onto the operating field of the eye and conditioning the reflections from the cornea so that interpretable images may be viewed by the surgeon as they look down the microscope. US Patent 5,135,299 describes a similar operating microscope featuring a head-up display, produced by reflecting operational information from the scleral portion of the eye.

It is an object of the present invention to provide an eye fixation method and apparatus that reduces the angular rotation of axis of astigmatism by providing a linear indicium or pattern of light.

It is another object of the present invention to provide a surgical visual feedback method and apparatus that provides increased information to the surgeon or operator.

According, therefore, to the present invention there is provided a method for aligning the axis of astigmatism of an eye including providing a target in the field of view of said eye so that said eye may fixate on said target, wherein said target includes or consists of an elongate element.

Preferably the target includes two elongate elements substantially perpendicular to one another, and more preferably the target includes a cross.

The target may include more than two elongate elements arranged as a grid.

The method may include providing said target by means of light emitting means.

Preferably said light emitting means includes a light emitting diode, and more preferably a plurality of light emitting diodes.

Preferably said method includes strobing said light emitting means.

The present invention also provides a fixation apparatus for aligning the axis of astigmatism of an eye including:

a target means for locating in the field of view of said eye so that said eye may fixate on said target; wherein said target includes or consists of an elongate element.

Preferably said target includes two elongate elements substantially perpendicular to one another, and more preferably includes a cross.

The target may include more than two elongate elements arranged as a grid.

The apparatus include light emitting means located on or forming said target.

Preferably said light emitting means includes a light emitting diode (LED), and more preferably a plurality of light emitting diodes.

Preferably said apparatus includes a printed circuit board (PCB), wherein said LED or LEDs are arranged on said PCB.

Preferably said apparatus is controllable to strobe said light emitting means.

The apparatus may include a pulsable power supply to strobe said light emitting means.

Further according to the present invention there is provided a method for supplying visual feedback during refractive surgery of an eye of a patient including:

1) providing an eye fixation means for said eye to fixate upon;

2) locating said eye for viewing by viewing means;

3) generating an information display of information pertinent to said surgery and suitable for displaying visually; and

4) transmitting said information display to said viewing means for viewing by said viewing means;

whereby said eye and said information display may be viewed simultaneously.

Preferably said method includes updating said information display.

Preferably step 3) includes generating said set of information

display with a controller means.

Preferably said controller means is a computer.

Preferably said method includes transmitting said information display to a display means and displaying said information display on said display means.

The display means may be a miniature TV or LCD screen or a plurality of LEDs.

Preferably step 1) includes the method for aligning the axis of astigmatism described above.

Preferably said viewing means includes left and right optics, and said target is located between the left and right optics means.

Preferably said viewing means is a surgical microscope.

The refractive surgery may be PRK or LASIK, thermal keratoplasty, intrastromal ablation or any other surgical method that alters the refraction of the eye.

The method may be performed with any laser suitable for use in surgery that involves altering the refractive properties of the eye, and preferably an ultraviolet ablation laser, a Holmium laser, or an Erbium laser at 3 microns.

Preferably step 4) includes viewing said information by means of a beam splitter or plate of glass.

The information may pertain to the status of the patient, to the surgery or to equipment, the position of the eye, or where an eye-tracker is aiming the laser.

The information may include operational information such as type of treatment, number of laser pulses required to finish, operation time remaining, patient identification and which eye is being treated.

The information may include microkeratome status information, such as suction and blade speed readings.

The present invention also provides an apparatus for supplying visual feedback during laser surgery of an eye including:

an eye fixation target for said eye to fixate upon;

viewing means for viewing said eye;

controller means for generating an information display; and

screen means for displaying said information display for viewing by said viewing means;

whereby said eye and said information display may be viewed simultaneously by an operator.

Preferably said refractive surgery is PRK or LASIK or other laser surgery that affects the cornea of the eye.

Preferably said apparatus includes display means for displaying said information display.

The apparatus may include a surgical laser.

The laser may be any laser suitable for use in surgery that involves altering the refractive properties of the eye, such as a ultraviolet ablation laser, a Holmium laser, an Erbium laser at 3 microns or any other appropriate laser source.

Preferably said target is the fixation apparatus for aligning the axis of astigmatism as described above.

Preferably said display means and/or screen means is viewed by means of a beam splitter or plate of glass.

Preferably said display means is a miniature TV or LCD screen or a plurality of LEDs.

Preferably said viewing means is a surgical microscope.

Preferably said controller means is a computer.

Preferably said viewing means includes left and right optics, and said target is located between the left and right optics.

The information may pertain to the status of the patient, to the surgery or to equipment, the position of the eye, or where an eye-tracker is aiming the laser.

The information may include operational information such as type of treatment, number of laser pulses required to finish, operation time remaining, patient identification and which eye is being treated, keratometry information, refraction information, and/or topographical information.

The information may include microkeratome status information, such as suction and blade speed readings.

In order that the invention be more fully understood, preferred embodiments will now be described, by way of example, with reference to the accompanying drawings in which:

Figure 1 is a schematic view of a eye fixation apparatus according to a preferred embodiment of the present invention; and

Figure 2 is a schematic view of an apparatus for supplying visual fe dback according to second preferred

embodiment of the present invention.

Referring to Figure 1, there is presented a schematic view of a patient's eye fixation apparatus 10 according to a preferred embodiment of the present invention. The apparatus 10 includes a fixation target in the form of a cross 12 formed by surface mounted light emitting diodes, LEDs 14. LEDs 14 are to allow the astigmatic patient to better judge horizontal and vertical directions, so that the axis of astigmatism is more naturally aligned.

Vertical axis 16 of the cross 12 of LEDs 14 is longer than horizontal axis 18. The LEDs 14 may alternatively be positioned to form any other pattern of elongate or linear elements, such as a line or a grid. The cross 12 may be placed between the stereo optics of a surgical microscope. Alternatively, it may be positioned elsewhere within the surgical laser, and projected to optically appear as if it is placed between the optics of the microscope.

In use, the patient is required to fixate his or her gaze on the flashing cross 12, thereby preventing angular rotation of the ocular globe and misalignment of the treatment eye's axis of astigmatism. The flash rate is about 1.5 Hz with a duty cycle of about 50%. The duty cycle may be adjustable to allow more light during LASIK and less light during PRK.

Figure 2 is a view of an apparatus 22 for supplying visual feedback according to a second embodiment of the present invention, for refractive surgery of an eye 24. The apparatus includes a fixation target 26, a surgical microscope 28, a head-up display 30 to give the surgeon feedback regarding patient fixation, the operating conditions and other pertinent information, and an imaging device in the form of miniaturized TV or LCD screen 32 (which may alternatively comprise a

combination of light emitting diodes), supplied within the laser delivery head (not shown). The head-up display 30 may be producing by projecting lights onto a surface, as is known in the art, and may be displayed on screen 32.

The apparatus 22 includes a controller in the form of computer 34 and communications link 36 between computer 34 and screen 32. Computer 34 generates the information content (comprising information pertinent to the operation being carried out) of the head-up display 30, and transmits this content via link 36 to screen 32 to display. This content could include a pulse countdown, operation time remaining, an alert signal indicating misalignment of the patient's eye, a cross indicating where the laser is currently aimed, patient information such as name or ID, treatment zone information, topographical information or any other information that the surgeon may deem useful.

The apparatus 22 further includes a beamsplitter 38, by which the head-up display 30 is viewed. The beamsplitter 38 forms a part of the optics of the laser (not shown), for relaying this information towards optical elements 40 and 42 of the microscope 28, so that the operator may see the information when he or she looks down the microscope 28.

Thus, in use, while the patient views a suitable fixation point 26 (such as a fixation cross as described above), the surgeon is able to view the patient's eye 24 and the head-up display 30 through the surgical microscope 28.

Hence, while preferred methods and apparatus according to the invention have been described, it will be clear to those skilled in the art that further modifications are possible, without departing from the spirit and the scope of the invention. For example, the fixation apparatus may be used in conjunction with the apparatus for supplying visual feedback.

The invention is therefore not limited by the embodiments described hereinabove.

DATED THIS 14TH DAY OF AUGUST 1998

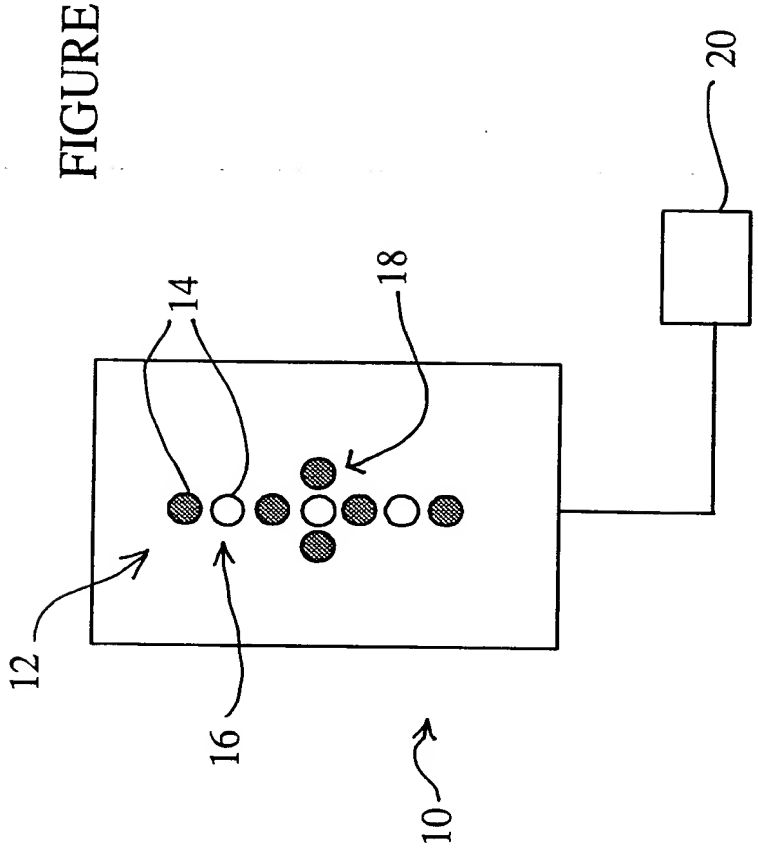
THE LIONS EYE INSTITUTE OF WESTERN AUSTRALIA INCORPORATED

By Its Patent Attorneys:

~~GRIFFITH HACK~~

Fellows Institute of Patent Attorneys of Australia.

FIGURE 1



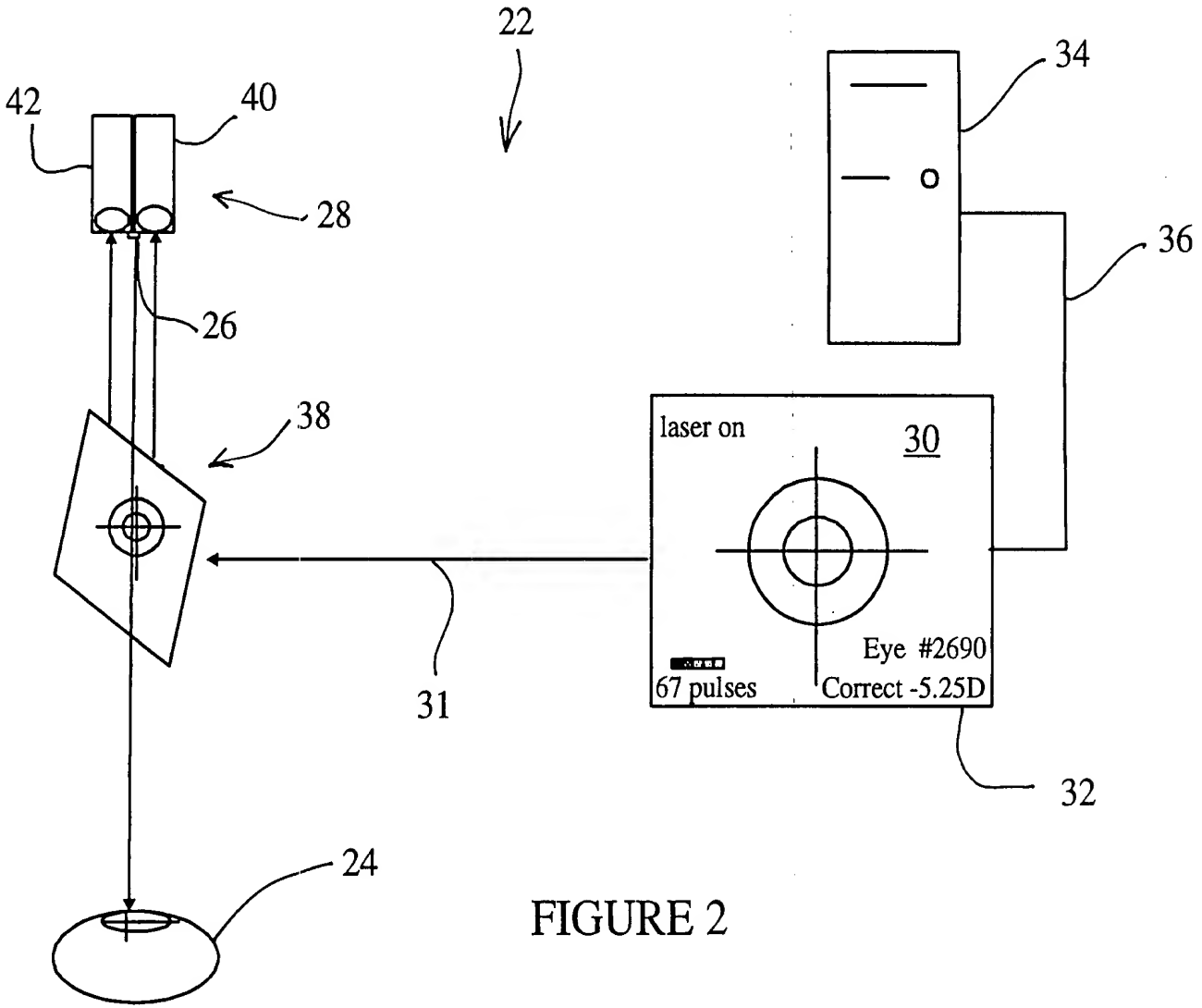

22
42
40
28
26
38
34
36
laser on
30
67 pulses
Eye #2690
Correct -5.25D
31
32
24

FIGURE 2